

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9010

Bartle, J.

February 17, 2013

Cynthia Carr ("Ms. Carr" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Harvey G. Carr, Ms. Carr's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Malcolm P. Taylor, M.D. Dr. Taylor is no stranger to this litigation. According to the Trust, he has signed at least 1,140 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated October 11, 2002, Dr. Taylor attested in Part II of Ms. Carr's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension.

3. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

Based on such findings, claimant would be entitled to Matrix B-1,⁴ Level II benefits in the amount of \$107,795.⁵

In the report of claimant's echocardiogram, Dr. Taylor stated that there was "[m]ild to moderate mitral regurgitation with RJA/LAA ratio of 24%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Taylor also opined that the claimant's "[left atrium] length = 5.93cm." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii).

In September, 2005, the Trust forwarded the claim for review by Maged M. Rizk, M.D., Ph.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Rizk concluded that there

4. Claimant concedes that her claim is payable, if at all, on the B Matrix because she ingested Diet Drugs for 60 days or less. See Settlement Agreement § IV.B.2.d.(2)(b).

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension is one of the complicating factors needed to qualify for a Level II claim.

was no reasonable medical basis for Dr. Taylor's finding that claimant had moderate mitral regurgitation because "[n]o [mitral regurgitation] is seen in real time." Dr. Rizk also concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension because the "[supero-inferior] diameter is overestimated."

Based on Dr. Rizk's findings, the Trust issued a post-audit determination denying Ms. Carr's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted a declaration of Jesse E. McGee, M.D., F.A.C.C., wherein he opined that there does not appear to be any overtracing of claimant's RJA or LAA and that "there is at least a RJA/LAA of 20% of the Mitral Valve." In addition, claimant challenged the auditing cardiologist's failure to provide any measurements as to claimant's level of mitral regurgitation and argues that without such measurements she "is

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Carr's claim.

put in a position where she can not [sic] contest the auditing cardiologist's characterization."⁷

The Trust then issued a final post-audit determination again denying Ms. Carr's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Carr's claim should be paid. On May 30, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6341 (May 30, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 7, 2006. Under the Audit Rules, it is within the Special Master's discretion to

7. Dr. McGee also opined that there was a reasonable medical basis for Dr. Taylor's finding of an abnormal left atrial dimension because claimant's left atrial dimension was "at least 5.93cm." Claimant further argued that her echocardiogram tape and report show that she had a left atrial measurement of 5.93 cm, and that the auditing cardiologist's opinion "is not reliable or scientific and amounts to mere guesswork and it should not be considered." Given our disposition with regard to the level of claimant's mitral regurgitation, we need not decide whether claimant has satisfied her burden of proving there is a reasonable medical basis for Dr. Taylor's representation that claimant had an abnormal left atrial dimension.

appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposition positions" is proper. Id.

In support of her claim, claimant reasserts the arguments raised during contest, namely, that she should prevail because two cardiologists found that Ms. Carr had moderate mitral regurgitation and that the auditing cardiologist should be required to provide measurements regarding his findings. In addition, claimant argues that "the auditing process is flawed" and that "the auditing cardiologists are not reviewing the cases objectively."

In response, the Trust argues that claimant's supplemental expert report is insufficient to satisfy her burden of establishing a reasonable medical basis for the conclusion that she had moderate mitral regurgitation. The Trust also asserts that Dr. Rizk conducted the audit in accordance with the Settlement Agreement and that the auditing cardiologist is not required to provide specific measurements.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's findings of moderate mitral regurgitation. Specifically, Dr. Vigilante found that:

In spite of this echocardiogram being a poor study, I was able to assess the presence and severity of mitral regurgitation in the early to mid portion of systole. Visually, there was no mitral regurgitation seen in the parasternal long-axis view. However, in the apical views a small jet of mitral regurgitation was seen in the early phase of systole in several cardiac cycles. Visually, trace to mild mitral regurgitation was suggested in these apical views. I digitized

those cardiac cycles in the apical views in which the mitral regurgitant jet was best evaluated and appeared to be most severe. I then digitally traced and calculated the RJA and LAA. I was able to accurately planimeter the RJA in the early to mid portion of systole. In both apical views, the mitral regurgitant jet was a short jet that did not reach the mid portion of the left atrium. In the apical four chamber view, the largest representative RJA was 1.1 cm². The LAA in the apical four chamber view was 16.7 cm². Therefore, the largest representative RJA/LAA ratio was less than 7%. The largest representative RJA in the apical two chamber view was 1.3 cm². The LAA in the apical two chamber view was 15.3 cm². Therefore, the largest representative RJA/LAA ratio was 8%. Most of the RJA/LAA ratios in the apical views were less than 5%. Therefore, the RJA/LAA ratio never came close to approaching 20%. There was one sonographer-determined RJA in the apical four chamber view. This measurement was 4.90 cm². This measurement was inaccurate and was a reflection of backflow. This was not a mitral regurgitant jet seen in real time. There were no sonographer-determined RJA's in the apical two chamber view. In addition, there was one sonographer-determined LAA of 20.55 cm² in the apical four chamber view. This was an inaccurate determination as the tracing went beyond the posterior wall of the left atrium. The inaccurate sonographer-determined RJA and LAA values are the same calculations documented in Dr. Taylor's echocardiogram report.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor's findings support a diagnosis of moderate mitral regurgitation because both the attesting physician and the Technical Advisor found an RJA of 4.90cm² and an LAA of either 20.53cm² or 20.55cm², "practically the exact same measurement." Ms. Carr also argues that the Technical Advisor did not adequately support his conclusion that the

attesting cardiologist measured backflow or traced beyond the posterior wall of the left atrium, and she argues that such a finding is inconsistent with Dr. McGee's declaration, which noted that there "appear[s]" to be no overtracing on the echocardiogram.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest Dr. Rizk's finding that the attesting physician's diagnosis of moderate mitral regurgitation lacked a reasonable medical basis because "no [mitral regurgitation] is seen in real time" on claimant's echocardiogram. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Carr relies only on Dr. McGee's conclusory declaration, which states that claimant has "at least a RJA/LAA of 20% of the Mitral Valve." Notably, neither Dr. Taylor nor Dr. McGee addresses Dr. Rizk's finding that the mitral regurgitation on which Dr. Taylor relied did not appear in real time. Claimant never identified any error in the auditing cardiologist's conclusion. Mere disagreement with the auditing cardiologist without identification of specific errors by him or her, however, is insufficient to meet a claimant's burden of proof.

Moreover, we disagree with claimant that Dr. Rizk did not adequately set forth the basis for his audit findings. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral

regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15 (Nov. 14, 2002). Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.⁹

We also disagree with claimant that the opinions of Dr. Taylor and Dr. McGee provide a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of those two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified

9. Claimant's demand for specific measurements is particularly hollow given that her own supplemental expert, Dr. McGee, did not provide any measurements and simply stated, without any substantive discussion or analysis, that claimant had "at least a RJA/LAA of 20% of the Mitral Valve." In any event, Dr. Vigilante, as part of his review, provided the specific measurements of the level of claimant's mitral regurgitation.

Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation.

See PTO No. 2640 at 9-13, 15, 21-22, 26. Here, Dr. Rizk determined in audit, and Ms. Carr does not adequately dispute, that claimant's level of mitral regurgitation was significantly overestimated because mitral regurgitation was not seen in real-time on claimant's echocardiogram. In addition, Dr. Vigilante reviewed claimant's echocardiogram and determined that the one sonographer-determined RJA measurement of 4.90 cm² was inaccurate because it included backflow and it did not appear in real time. He also observed that the one sonographer-determined LAA measurement of 20.55 cm² was inaccurate because "the tracing went beyond the posterior wall of the left atrium." Finally, Dr. Vigilante noted that these are the same measurements Dr. Taylor included in his echocardiogram report. Claimant does not refute these specific findings. Instead, she relies on Dr. Taylor's echocardiogram report based on these inaccurate measurements and Dr. McGee's declaration that does not provide any measurements of his own.¹⁰ Measurements based on such

10. We disagree with claimant that Dr. McGee's observation that (continued...)

unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation.

Claimant's argument that Dr. Vigilante's conclusions provide a reasonable medical basis for her claim because he determined the echocardiogram demonstrated an RJA of 4.90 cm² and an LAA of 20.53 cm² is misplaced because Dr. Vigilante did not make any such determination. To the contrary, he concluded that the largest representative RJA in the apical four chamber view was 1.1 cm² and the largest RJA in the apical two chamber view was 1.3 cm². In addition, he determined the LAA in the apical four chamber view was 16.7 cm² and 15.3 cm² in the apical two chamber view. Moreover, Dr. Vigilante specifically noted that the sonographer's RJA measurement of 4.90 cm² was inaccurate and was a reflection of backflow, and that the sonographer's LAA measurement of 20.55 cm² was inaccurate because the tracing went beyond the posterior wall of the left atrium.

Finally, we reject claimant's assertion that the Trust's audit system is unfair to claimants. It is claimant's burden in the show cause process to show why she is entitled to

10. (...continued)
there did not appear to be any over measurement of Ms. Carr's RJA or LAA undermines Dr. Vigilante's findings. As an initial matter, Dr. McGee did not provide any of his own measurements. In addition, Dr. McGee has submitted declarations on behalf of several claimants in the show cause process. Each declaration has consisted of the same text, repeating claimant's name and the date of the echocardiogram and noting that the RJA and LAA measurements do not appear overtraced and that claimant has at least a 20% RJA/LAA ratio.

Matrix Benefits. See Audit Rule 24. The audit and show cause process, as approved by this court, provides claimant with notice and an opportunity to present her evidence in support of her claim.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Carr's claim for Matrix Benefits and the related derivative claim submitted by her spouse.